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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,456	02/19/2004	Denisa D. Wagner	CFBF-P02-015	5162

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EXAMINER	
GAMBEL, PHILLIP	
ART UNIT	PAPER NUMBER
1644	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/782,456	WAGNER ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22 and 50-56* is/are pending in the application.

4a) Of the above claim(s) *6,8,10,11,19-21,51 and 54-56* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7,9,12-18,22,50,52 and 53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

1. Applicant's election of Group I, drawn to methods of treating hemostasis and disorders with P-selectin and the species of "P-selectin activity increasing the levels of P-selectin in plasma and Hemophilia A in the Response to Restriction Requirement, filed 10/12/2006, is acknowledged.

Upon a prior art search, the species have been extended in the context of to methods of treating hemostasis and disorders with P-selectin.

Claims 1-22 and 50-56 are pending.

Claims 1-5, 7, 9, 12-18, 22, 50, 52 and 53 are under consideration as they read on the elected Group I, drawn to methods of treating hemostasis and disorders with P-selectin.

Claims 6, 8, 10, 11, 19-21, 51 and 54-56 have been withdrawn from consideration as they read on non-elected Groups and species.

Claims 23-49 have been canceled previously.

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Applicant should restrict the title to the claimed invention.

Applicant should avoid the use of novel in the title, as patents are presumed to be novel and unobvious.

3. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected.

Trademarks should be capitalized or accompanied by the ® or™ symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

4. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-5, 7, 9, 12-18, 22, 50, 52 and 53 are rejected under 35 U.S.C. 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed.

The specification as originally filed does not provide sufficient written description for the genus of "inducers of P-selectin activity" in methods to induce hemostasis.

Applicant has not provided sufficient biochemical information (e.g. amino acid sequences, etc.) that distinctly identifies the genus of "inducers of P-selectin activity" as broadly encompassed by the claimed invention.

As page 8, paragraph 2 of the instant specification discloses,
the "inducer of P-selectin activity" can act to increase the plasma level of soluble P-selectin, to stimulate the translocation of P-selectin from a cellular storage pool to the cell surface, to increase the proteolytic cleavage and to release of soluble P-selectin from the surface of a cell expressing P-selectin, and/or to increase p-selectin gene expression by stimulating either gene transcription or translation.

It is noted that applicant's election is drawn to soluble P-selectin and P-selectin fusion proteins, which appears to have the ability to induce hemostasis and, in turn, which appears sufficient written description.

However, there is insufficient written description of a sufficient number of species to satisfy the genus, particularly in the absence of defining the relevant identifying characteristics such as the structure of other physical and/or chemical characteristics of the claimed genus and, in turn, there is insufficient written description of such identifying characteristics of the claimed genus of "inducers of P-selectin activity", including the various activities described in the specification as filed (again, see page 8 of the instant specification) in the specification as filed, commensurate in scope with the claimed invention.

Even with soluble P-selectin, the objective evidence is not clear whether soluble P-selectin acts via some, all or none of the disclosed or claimed characteristics of "inducers of P-selectin activity".

Further, the instant specification discloses that anti-PSGL-1 antibody is "an inducer of P-selectin".
However, this assertion appears in contrast to the general acceptance in the art that anti-PSGL-1 antibodies were *inhibitory or neutralizing* in therapeutic regimens and not *stimulatory* with respect to P-selectin interactions at the time the invention was made. For example, see columns 18-19 U.S. Patent No. 5,840,679 concerning neutralizing or inhibitory properties of anti-PSGL-1 antibodies.

It is noted that Skolnick et al. (Trends in Biotech. 18(1):34-39, 2000) teach that the skilled artisan is well aware that assigning functional activities for any particular protein or protein family based upon sequence homology is inaccurate, in part because of the multifunctional nature of proteins (e.g., "Abstract" and "Sequence-based approaches to function prediction", page 34). Even in situations where there is some confidence of a similar overall structure between two proteins, only experimental research can confirm the artisan's best guess as to the function of the structurally related protein (see in particular "Abstract" and Box 2).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016 (Fed. Cir. 1991).

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483.

The Court further elaborated that generic statements are not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. Finally, the Court indicated that while applicants are not required to disclose every species encompassed within a genus, the description of a genus is achieved by the recitation of a representative number of molecules falling within the scope of the genus, See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicant is relying upon certain biological activities and the disclosure of a limited number of species, particularly P-selectin to support an entire genus. Yet, the instant specification does not provide sufficient written description as to the structural features of said inducer of P-selectin activity", as currently encompassed by the instant claims. Also, the specification does not provide for a sufficient correlation between the chemical structure and the function of the genus of "inducers of P-selectin activity", including the correlation to any, all or some of the claimed characteristics of "inducers of P-selectin activity", currently encompassed by the claimed invention. The specification as-filed does not provide a sufficient written description for "inducers of P-selectin activity", commensurate in scope with the claimed invention.

Mere idea ~~or function is insufficient for written~~ description; isolation and characterization at a minimum are required

The instant claims do not provide sufficient structural and functional characteristics coupled with a known or disclosed correlation between function and structure. Since the disclosure fails to describe the common attributes or characteristics sufficiently that identify members of the genus of "inducers of P-selectin activity".

The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement make clear that if a claimed genus does not show actual reduction to practice for a representative number of species; then the Requirement may be alternatively met by reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 column 3).

In the absence of structural characteristics that are shared by members of the genus of "inducers of P-selectin activity", the skilled artisan would conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus. See University of California v. Eli Lilly and Co. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997).

"Adequate written description requires a precise definition, such as by structure, formula, chemical name or physical properties, not a mere wish or plan for obtaining the claimed chemical invention." Id. at 1566, 43 USPQ2d at 1404 (quoting Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606).
Also see Enzo-Biochem v. Gen-Probe 01-1230 (CAFC 2002).

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

8. Methods of inducing hemostasis in a subject with soluble P-selectin and P-selectin fusion proteins appear to be free of the prior art and appear to be allowable; if limited as such.

The following pertinent reference Grunewald et al. Trends in Molecular Medicine 10: 9-10, 2004, indicating the ability of P-selectin and P-selectin immunoglobulin fusion protein appears relevant for hemorrhagic disorders in humans, including the treatment of hemophilia.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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